



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 11, 2000

Eric M. Mittleberg, Ph.D.
Vice President, Scientific Affairs
Zenith Goldline Pharmaceuticals
140 Legrand Avenue
Northvale, NJ 07647

Dear Dr. Mittleberg:

Your petition requesting the Food and Drug Administration to issue a statement clarifying that all abbreviated new drug applications containing paragraph IV certification delivered to FDA's Office of Generic Drugs on the same business day are submitted at the same time for 180-day exclusivity purposes was received by this office on 08/09/00. It was assigned docket number 00P-1445/CP 1 and it was filed on 08/11/00. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Gaffe
Dockets Management Branch

00P-1445

ACK 1